Genetically Engineered Trees: Promise and Concerns

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RESOURCES FOR THE FUTURE

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1. Introduction

The Animal and Plant Health Inspection Service (APHIS) of the U.S. Department of Agriculture has been regulating biotechnology since 1987, overseeing more than 10,000 genetically engineered crop field tests and deregulating 61 genetically engineered plant varieties (Veneman 2004). For many years, USDA derived its authority for genetically altered plants from the Federal Plant Pest Act of 1957 and some earlier statutes that provided the department with regulatory authority over the movements of plants, plant products, and plant pests into, within, or through the United States Effective June 22, 2000, those statutes were repealed and replaced by the Plant Protection Act (Title 7 U.S.C. Sections 7701 *et seq.*), which currently provides the basis for APHIS's authority over genetically engineered organisms (Bryson et al. 2001). The Plant Protection Act (PPA) provides statutory authority to APHIS to regulate a genetically altered plant, crop, or tree on its potential to become a plant pest or pose unacceptable risks to the environment.

APHIS administers regulations for most genetically engineered plant organisms, which are initially classified as "regulated articles." Developers of regulated articles must obtain prior authorization from APHIS for the importation, interstate transport, and field-testing of these plants. Field-testing is a precondition of deregulation, which in turn is necessary for the transgenic to be commercialized without restrictions. Based upon the results of field tests and other information, an APHIS scientific committee determines whether to deregulate specific transgenic plants. Once a determination of nonregulated status is made, the product and its offspring no longer require APHIS authorization for movement, release, or commercialization in the United States.

In January 2004, USDA announced (USDA 2004) its "intention to update and strengthen its biotechnology regulation for the importation, interstate movement and environmental release of certain genetically engineered (GE) organisms." Associated with that announcement, Secretary of Agriculture Ann Veneman (2004) noted that a regulatory framework must advance with the science and technology and announced that APHIS was beginning a comprehensive update of their regulatory framework, with greater emphasis to be put on risk and additional flexibility for products that have already demonstrated their safety. As part of the overall process, APHIS was to prepare an environmental impact statement (EIS) on its biotechnology regulations. The EIS would provide a broader coverage of risks and benefits as part of an updated protocol for trees (Cordts 2004).

This announcement coincided with the release of a National Academies of Science (NAS) study, *Biological Confinement of Genetically Engineered Organisms* (2004), which recommended that greater regulatory consideration be devoted to methods of "bioconfinement," such as induced sterility, which would prevent transgenic plants and animals from escaping into natural ecosystems. The NAS committee paid particular attention to a number of transgenic plants, fish, and microbes.

USDA's general approach in updating its biotechnology regulation is to collect public comments via a *Federal Register* notice. The two major comment options were to continue the current system or to revise and update it, addressing the scientific advances in biotechnology and also applying the new authorities provided to APHIS as part of the PPA (2000). The general expectation is that, should public comments desire an updating, the regulations will be revised so as to more adequately address the scientific advances in biotechnology, new trends in biotechnology, and to apply the newly granted APHIS under the PPA. This includes considering allowing conditional deregulation, which would require additional monitoring for some period of time.

Another possibility, often encouraged by biologists but generally believed to be less likely for approval, would be the establishment of a multi-tiered permitting structure where different levels of permits would be assigned based on the risk associated with the different organisms. The risk would be determined by a variety of criteria that would be applied to those organisms. This revision of the deregulation process would be designed to allow new flexibility and provide for the streamlining of the system thereby allowing the evaluation and deregulation resources to focus oversight based on risk.

Since revisions to biotechnology regulation are in process, the discussion of this report is focused on the APHIS system as it has existed, and, to the extent feasible, on prospective changes that appear likely on the basis of the announced goals and given the information available at the present time.

2. Objectives of the Report

This report focuses on the implementation of the PPA (Title 7 U.S.C. Sections 7701 *et seq.*) and related regulations as the Act has been applied to transgenic trees. A plant that involves the insertion of a gene using a nonsexual approach is considered a bioengineered plant and defined as a transgenic. The focus is largely on forest trees, as opposed to fruit trees, ornamental trees, or trees oriented to bioremediation. The perspective examined is multiple and includes: a description of the Act and how it is being implemented by APHIS; the reactions to the regulations by a variety of groups including tree breeders and developers; users of both the prospective unregulated products, that is, both tree germplasm and products from transgenic wood; environmentalists; and others.

The original purpose of this report was to examine the effects of the PPA, as administered by APHIS, with respect to the regulation of trees, specifically trees used for wood production. Part of the purpose of this report was to examine situations where deregulation had occurred. To date APHIS has authorized thousands of field tests for more than 50 plant species, mostly agricultural crops, and many of these have achieved deregulated status. However, despite its considerable experience regulating crop plants, APHIS has only limited experience with trees. As recently as 2000, only 124 field tests of genetically altered trees have been authorized (McLean and Charest 2000).

It should be noted that the basic APHIS deregulation process for trees is identical to that for other plants, including annual crops, although the time frame of the field tests and other investigations may vary. The tree developer must obtain an acknowledgement from APHIS to field test, provide the results of the field tests to APHIS and support the petition with various other types of information such as literature and statistical test results.

The outcomes associated with the PPA were an important element that I intended to focus on. In this case, that would have involved an assessment of the postregulatory results. Unfortunately, only one tree—an orchard tree, the papaya—has achieved deregulated status. The circumstances surrounding that deregulation and the transgenic tree's fate are discussed. The report describes the implementation and outcomes of procedures related to the authorized field tests for transgenic trees and a description of the types of tests and how they are evaluated. Consequently, my inquiry here must be limited to examining the functioning of the PPA with respect to the deregulation of transgenic trees, even though essentially none of the timber trees has yet to successfully negotiate the entire APHIS regulatory system.

Given these limitations, the report systematically examines the licensing and other practices required for deregulation, a condition for the commercialization of genetically modified trees. This report describes the existing regulatory system, but it must be noted that this system is in a state of flux. Consequently, I try to identify those areas of the process likely to be affected by the regulatory updating.

Also, the report details the concerns about procedures, processes, and conditions, both formal and informal, whereby "regulated articles," that is, the transgenic trees, are deemed to be safe or unsafe. The role and degree of risk accepted in the deregulation process is discussed. While the research focuses on the assessment required under the PPA, it is also mindful of legislation to examine the wider environmental assessment under the National Environmental Policy Act (NEPA) of 1969 (Title 42 U.S.C. sections 4321 *et seq.*). It describes how the NEPA is considered, both formally and informally, within the PPA regulatory process undertaken by APHIS. It also discusses briefly the substantial role of the Environmental Protection Agency (EPA) and the extent to which that agency influences regulatory decisions of APHIS.

Additionally, the report briefly discusses regulatory systems in countries other than the United States, including Canada, the European Union, and China, to provide a comparative perspective. The intercountry comparison is particularly useful in its discussion of the comparative role and degree of risk that is acceptable to the various countries in their deregulation processes.

The report begins by providing a historical context within which the role of transgenic or GE crops and trees may be examined, with a focus on forestry. Note that for this report, the more commonly used term genetically modified organism, or GMO, will be replaced by genetically engineered, because traditional breeding techniques can generate "genetically modified" organisms. The role of natural forests and the transition to planted and intensively managed forest is reviewed. It is within this context that the *potential* role of transgenic or genetically engineered trees is examined and evaluated. The *potential* benefits and costs—both economic and environmental—associated with transgenic trees are discussed and evaluated. *Potential* is stressed since the commercial use transgenic trees have not yet been introduced in the United States, although commercialization is reported to have begun in China and is imminent in South America.

3. Background

Humans have been striving to improve their ability to survive though modifications and innovations in their access to food and fiber for countless millennia. Hunting and gathering gradually gave way to herding and primitive farming. As Bradshaw (1999) points out, the domestication of a small number of plants, particularly wheat, rice, and maize, is among the most significant accomplishments in the human era. Modern civilization would be impossible without this innovation. Common features associated with plant domestication include high yields, large seeds, soft seed coats, nonshattering seed heads that prevent seed dispersal and thus facilitate harvesting, and a flowering time that is determined by planting date rather than by natural day length.

Output increases, driven by biotechnological improvements, continued to be experienced through time. The enhancement experienced in maize and potatoes in pre-Columbian American reflect human selection and breeding practices oriented toward improving productivity and other desired traits. In a more recent example, Hayami and Ruttan (1985) point out that land productivity in grain production in the United States showed little increase in the two centuries prior to 1930, as most of the gains were due to innovations such as new equipment and mechanization, that allowed more land to come into production. While over the same period land productivity in Japan was a function of biotechnological improvements in the form of improved seed and increased yields.

However, in the United States after the 1930s, when most of the best agricultural land was already in use, the focus of innovation was redirected to plant improvement, which increased land productivity through higher yields.

Until recently these improvements were achieved through the use of traditional plant breeding techniques, which gradually increased agricultural yields (Sedjo 1999a). Transgenic plants have already had an important impact on a number of agricultural products, including corn, soybeans, and cotton. The past decade or so has seen continuing increases in biological productivity, especially in agriculture, driven, at least in part by genetically modified crops (FAO 2004). In many cases improvement achieved through traditional breeding are augmented by modern genetic modification. For example, the increased productivity of the soybean has been achieved through traditional breeding, while its resistance to herbicides, a characteristic that allows the more efficient and effective application of herbicides, is the result of genetic modification that imparted herbicide resistance.

Forestry today is following the pattern very similar to that established over the past several millennia in agriculture. Early food was collected from the natural ecosystem, but this was gradually changed to deliberate herding and planting of crops. Eventually, seed from one region was transported to another region where, often, it flourished. Forestry only recently began a serious transition from gathering (harvesting natural forests) to cropping (planting and managing) trees (Table 1).

However, unlike many agricultural crops, trees have only been partly domesticated for wood production in the last half-century (El-Kassaby 2003). They have been domesticated for fruit and ornamental purposes for hundreds if not thousands of years. Early tree planting benefits were often derived from the superior growth productivity regularly observed in introduced exotics, which frequently thrived in their new environments (Table 2). Although exotics have not played a major role in U.S. forest production, their success abroad—in South America and Oceania, for example—provided an impetus for improving domestic trees to increase domestic productivity (Sedjo 1999a, 2004b, 2004d)

Only after trees were being planted for commercial purposes did it seem to pay off to undertake the investments necessary for serious efforts to increase their productivity. Once a decision is made to invest in planting, a reasonable follow-on is to choose to plant a highly valued species and one that has the characteristics to generally improve financial returns. Today improved or superior trees are increasingly being planted and are in fact the norm in the United States. In many other countries, the emphasis is being placed on improving exotic species that have become the dominant commercially planted trees.

Table 1. Transitions in Technology and Forest Management

Type	Period
Wild forests	10,000 BCE (or earlier) to present
Managed forests	100 BCE to present
Early Planted forests	circa 1800–1900
Development of principles of inheritance by Gregor Mendel	mid to late 1800s
Development of commercial hybrids (crops)	1930s
Planted, intensely managed forests	1960 to present
Planted, superior trees from traditional breeding techniques	1970 to present
Planted, superior trees from clones	1990 to present
Field trials, GE trees	1990 to present
Commercial plantings, GE forest trees	2005? to future

Planting and improved genetic stock is associated with management intensity. Contemporary planted forests are akin to agricultural cropping. Sites are prepared, seedlings planted, vegetative control undertaken, fertilizer applied where needed, precommercial and commercial thinning done, followed by a final harvest, after which the cycle repeats itself.[1] A logical next step would be the introduction of transgenic, or GE, trees, with the agricultural cropping model demonstrating the approach. To begin this next step, appropriate new technology must be developed and be financially viable, the trees must meet the deregulated hurdle, and there must be some degree of public acceptance (Sedjo 2004c).

[1] Selection harvesting is practiced for some forest types and tree species in which the rotation cycle is more complex.

Table 2: Worldwide Timber Yields

Site	Yield (m3/ha/yr)	Rotation (years)
Temperate and boreal softwood forests		
Canada average	1.0	–
British Columbia	1.5–5.3	–
Sweden average	3.3	–
Finland	2.5	60–100
Russia	1.0–2.9	–
Siberia	1.0–1.4	70–200
Softwood Plantations		
Britain (Sitka Spruce)	14	40
South Africa (Pine spp.)	10–25	20–35
New Zealand (Monterey Pine)	18–30	20–40
East Africa (Pine spp.)	25–45	20–30
Brazil (Pine spp.)	15–35	15–35
Chile (Monterey Pine)	20–30	15–35
Tropical Hardwoods		
Malayan dipterocarp forest	up to 17	–
Mixed tropical high forest	0.5–7.0	–
Teak plantations	14	40–60

Source: Clapp, R.A.F. 1993.

The Current Situation and Some Opportunities

Plantations forestry has already demonstrated that it has the potential not only to dominate industrial wood production, but also to help protect and conserve of much of the natural forest and the environmental and ecosystem services they provide (Sohngen et al. 2001). Today, plantation forests have become an important source of timber, accounting for about one-third of the harvested industrial wood by the end of the 20th century (FAO 2000), and have the potential to dominate industrial wood production in time. This contrasts dramatically with the situation just 50 years ago when planted forests accounted for a negligible portion of the world's industrial wood harvest. The role of GE trees is to enhance that advantage.

In addition to providing wood at a lower cost, high-yield planted forests have the potential desirable environmental side-effect of drawing timber harvests away from natural and old-growth forests, allowing them to be used for nontimber, environmental purposes (Sedjo and Botkin 1997). The continuation of the shift toward the replacement of natural timber by intensively managed planted forests provides the possibility of the stabilizing the area of the world's natural forest at roughly current levels (Victor and Ausubel 2000).

While the changes in forestry mirror those that in agriculture over millennia, in forestry almost all of these changes have occurred relatively recently. Although traditional breeding approaches to tree improvement have become common in forestry over the last several decades, it is only in the past decade that major efforts have been undertaken to develop transgenic trees.

In opening the opportunities for high productivity forestry, with control from seedling to harvest, plantation forestry has created the preconditions necessary to financially justify tree improvement through both traditional and modern transgenic breeding. As with agriculture, forest cropping involves intensive management and control over the inputs, including the choice of the germplasm to be planted. Over the past 30 years considerable improvements have been made in forest stock utilizing traditional breeding approaches. Forest biotechnology, including genetic engineering, is in its infancy. However, introduced genes in transgenic trees give great promise of providing for the expression of desired traits and thereby increasing productivity, increasing product quality and expanding the range of and types of land and climatic conditions under which production forests can thrive.

Genetic engineering has already had a huge effect on agriculture. In 2003 GE crops were planted on 167 million acres worldwide, with their area of planting having been expanded by 15 percent each years in the most recent two years. This includes three million hectares of GE soybeans in Brazil, which officially approved planting for the first time in 2003 (James 2003). GE crops account for over 100 million acres in the United States and include 81 percent of U.S. soybeans, 40 percent of U.S. corn and 73 percent of all U.S. cotton (Pew 2003a).

Although agricultural use of GE crops is expanding rapidly, its use continues to be highly contentious. For example, the European Union's (EU) Regulatory Committee did not approve the importation and process of "GT73," a transgenic canola, even though the European Food Safety Authority had earlier assess the product as safe (CropBiotech 2004). [2] However, the most recent negotiations under the World Trade Organization suggest that the EU market will increasingly allow GE agricultural products to be imported, although they will likely need to be labeled as genetically engineered.[3]

As noted, much of the biotechnology already developed for agriculture has direct applications in forestry. Innovations such as the introduction of the herbicide-resistant gene into tree seed stock follow directly from the success of herbicide- resistant gene in crops. Research similar to that in agriculture is also being undertaken with disease and pest-resistant genes, as well as other gene-altering modifications. It is anticipated that these innovations could result in substantially reduced timber costs, through increased wood productivity and the reduction of plantation establishment costs and reduced trees losses through the growing cycle. Also, biotechnological research in forestry is moving in the direction whereby the genetic alteration would enhance wood quality by desired modification in fiber characteristics and modifications in other trees characteristics, such as lignin content or limb thickness, in a manner that would reduce processing costs. All of these modifications have the potential to generate financial benefits through reduced production costs and enhanced productivity.

[2] This finding is consistent with the broader earlier findings of no damages of the Subcommittee on Basic Research (2000). See also www.europabio.org/pages/index.asp.

[3] It is less likely, however, that many EU countries will permit the domestic planting of large volumes of GE crops.

4. Biotechnology and Genetic Modification

Traditional Breeding

Selection and Breeding Orchards

Tree improvement most often has relied on traditional breeding techniques like the selection of superior trees for volume increases and stem straightness and on the grafting of these traits into breeding orchards and producing seed orchards. When breeding orchards begin to flower, pollination of selections is artificially controlled, seeds are collection, progeny tests are established, and the best offspring are selected for the next cycle of breeding. By identifying and selecting for desired traits, breeding can choose a set of traits that can improve wood and fiber characteristics, improve tree form, improve growth and provide other desired characteristics. Experience has shown that an orchard of first-generation, open-pollinated seed can be expected to generate an 8 percent per generation improvement in desired characteristics. More sophisticated seed collection and deployment techniques, such as collecting seed from the best mothers (family block), can result in an 11 percent increase, while mass-controlled pollination techniques, which control for both male and female genes (full sibling), have increased yields up to 21 percent.[4]

Hybridization

A variant of traditional breeding technique widely used in forestry is that of hybridization, which has provided robust offspring by bringing together populations that do not normally mix in nature. Tree hybrids are often a means to improve growth and other desired characteristics. Crosses of trees unlikely to breed in nature often exhibit growth and other characteristics not found in either parent population.

Cloning and Vegetative Reproduction

Vegetative reproduction[5] comprises a broad range of techniques involving the manipulation of plant tissue that ultimately allows for vegetative reproduction of the

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[4] Westvaco Corporation, conversation with reseachers in spring 1997.

[5] Some techniques related to cloning and tissue culture are commonly viewed as biotechnology, although not genetic engineering.

whole plant. This can broadly refer to clonal techniques for growing plant tissue or part in a nutrient medium containing minerals, sugars, vitamins, and plant hormones under sterile conditions. However, for some tree species, particularly conifer, cloning approaches in the past have been limited (Pullman et al. 1998).

The development of cloning techniques in forestry is important for a number of reasons. First, an approach must be developed to allow the propagation of large numbers of seedlings of superior trees. Second, for genetic engineering of trees, the clone provides a vehicle through which desired foreign or artificial genes can be transferred. That is, a clone is a vehicle for mass production of the transgenic plant (see the Clonal section below).

Biotechnology

Biotechnology has been defined as having five major categories. These are: 1) markers; 2) propagation and multiplication; 3) functional genomics; 4) marker-aided selection/breeding; and 5) genetic modification (El-Kassaby 2003). This report focuses largely on the fifth, with some discussion of propagation and multiplication as applied to trees. The role of propagation and multiplication as enabling technology to genetic modification is the main reason for its inclusion in this report. As stated earlier, a genetically modified plant that involves the alteration of the genome by the insertion of a gene using a nonsexual approach is defined as a bioengineered or genetically engineered plant and defined as transgenic.

Desired Beneficial Traits for Transgenic Trees

High productivity plantation forestry, with control from seedling to harvest, has created the preconditions necessary to financially justify tree improvement through both traditional and modern transgenic breeding. The financial and economic benefit associated with transgenic trees would be though increased productivity, increased quality, and lower costs, at least one of which would be expected for the innovation to be developed and adopted.

Over the past 30 years considerable improvements have been made in forest stock utilizing traditional breeding approaches. Although forest biotechnology, including genetic engineering, is in its infancy, planted forests offer incentives for the improvement of stock through the addition of desired traits, including the following and Table 3 below:

- Fiber/Lignin modification
- Flowering Control
- Disease Tolerance
- Wood density
- Herbicide tolerance
- Growth
- Stem straightness
- Nutrient uptake
- Cold, wet, and/or drought tolerance
- Insect tolerance

The focus of recent research appears to be on first three traits of the list. The first, fiber/lignin modification, would enhance productivity and reduce processing costs in pulp production. Flower control would be designed to limit gene escape, while disease tolerance for America chestnut blight is one focus of research on disease tolerance.

Table 3. Forest Traits that Can Be Improved through Biotechnology

Silviculture	**Adaptability**	**Wood Quality Traits**
Growth rate	Drought tolerance	Wood density
Nutrient uptake	Cold tolerance	Lignin reduction
Crown/stem	Fungal resistance	Lignin extraction
Flowering control	Insect resistance	Juvenile fiber
Herbicide		Branching

Source: Context Consulting.[6]

Although the list and table suggest a wide range of transgenic possibilities for trees, in very recent years the targets of interest for genetic engineering in trees have tended to focus on lignin and/or cellulose modification and herbicide resistance. The

[6] Context Consulting provided information on potential innovations and their likely cost implications based on the best judgment of a panel of experts. Their information was used for this table and the list of traits above.

former is of great interest to the pulp and paper industry. Attempts are under way to reduce lignin context or vary the lignin-to-cellulose composition for easier lignin removal. Some work suggests that a reduction of lignin content can be accompanied by an absolute increase in the volume of cellulose (Fladung forthcoming).

A second potential of genetic engineering is establishing genes resistant to insects, fungi, and herbicides. The Bt (*Bacillus thuringiensis*) gene, as in agriculture, has also been show to be very effective in tree protection against insect pests (Tiang et al. 1994). Also, there has been considerable interest in the application of the glyphosate herbicide-resistant gene, which has been highly successful in agriculture, to trees.

5. The Potential Benefits of Transgenics in Plantation Forests

Plantation forests are highly attractive because they offer potential many types of financial, economic, and societal benefits.

Potential Economic Benefits

The prospective benefits from biotechnology in trees would be expected to result from the careful complementary and coordinated development of both traditional breeding and genetic engineering. A superior tree, that is, the best tree for these purposes resulting from traditional breeding would provide the basic tree into which the desired genes would be asexually introduced. The introduction of the desired traits into the already superior tree gives great promise of providing for the expression of those traits thereby increasing productivity, increasing product quality, and expanding the range and types of land and climatic conditions under which productive forests can thrive. Many of the desired traits involve changes in the wood fibers to either increase their volume or to make them more amenable to the processing necessary to convert wood fiber into wood pulp, used in paper production.

For example, the interest of the industry is to reduce costs and minimize the ecological demands when using highly reactive chemicals in the process of removing the lignin.

As noted, desired industrial innovations possible through genetic engineering include increased fiber per volume of tree wood, reduced lignin (which must be separated from the fibers) in the tree, lignin that is easier and therefore less costly to remove, improved characteristics of juvenile fiber so as to make them more usable, and so forth. In addition, tree form is important for both pulpwood, but especially saw timber, for producing desired products. Straight stems or trunks, thin limbs, and adequate density are generally viewed as desirable.

Table 4 provides possible financial gains and operating costs estimated to be associated with various tree biotechnology innovations. The first of these innovations—a low-cost, pine cloning technique—is a biotechnological, but not a transgenic, innovation, and is discussed in more detail later in this report. The second innovation will act to improve lumber strength. The third relates to the use in trees of an herbicide-resistant gene, such as now is in common use for some crops.[7] The last three innovations are related to changes that will enhance the quality or volume if wood fiber or reduce costs of processing it in a wood pulping digester.

Table 4. Possible Financial Gains from Future Biotech Innovations

Additional Innovation	Benefits[8]	Operating Costs
Clone superior pine	20% yield increase after 20 years	$100/hectare or 15–20% increase
Wood density gene	Improved lumber strength	None
Herbicide tolerance gene in eucalyptus (Brazil)	Reduce herbicide and weeding costs potentially saving $350 or 45% per hectare	None
Improve fiber characteristic	Reduce digester cost potential savings of $10 per cubic meter ($m^3$).	None
Reduced amount of juvenile wood	Increase value $15 per m^3 (more useable wood)	None
Reduce lignin	Reduce pulping costs potential of $15 per m^3	None

Source: Context Consulting.

The introduction of a herbicide-tolerant gene into tree seed stock, for example, follows directly from the success of the introduction of the same herbicide tolerant gene in agriculture. One study suggested a potentially huge market for such a product

[7] The usual practice is to use the herbicide on the land before planting and again shortly after planting, thus reducing weed competition early in the crop or tree growth cycle. There is evidence that for some crops, such as cotton, the total application of the herbicide is reduced.

[8] The actual cost savings experienced by the tree planter will depend on the pricing strategy used by the gene developer and the portion of the savings to be captured by the developer and passed on to the grower.

(Sedjo 1999). However, given that herbicide-resistant, GE trees would probably need to be deregulated anew in each country and that the benefits are greatest for deciduous trees, which are not a major part of U.S. planted forests, the realistic market size is probably much more modest than in the global market as a whole and the interest in herbicide-resistant, transgenic trees appears to have waned.

Other possibilities exist but are generally viewed as lower priority, at least within the United States. For example, there is the possibility of a transgenic with a Bt gene, which would provide resistant to pests.[9] However, the dual deregulation process in the United States, both APHIS and EPA (since the latter has responsibility for pesticides and toxics), together with concerns about the environmental implications of escape of Bt genes into the natural environment, appears to have tempered enthusiasm for the Bt tree within that country.

The cropping mode of fast-growing planted forests is now out competing harvests from natural and second-growth forests. This is due to the reduced costs of harvesting because of the accessibility of well-located planted forests. Fast-growing, intensively managed planted forests have shown remarkable growth rates, eliminating the necessity of moving to new forest locations. Also, the set-aside of many natural old-growth and second-growth forests and the greater stringency of harvest regulations have made harvesting natural forest increasingly costly. For these reasons planted forests have gradually been replacing natural forests as the source of industrial wood. Today, intensively managed planted forests, which have demonstrated the ability to substantially increase biological yields, are gradually becoming an important source of timber and have the potential to dominate industrial wood production (Sohngen et al. 1999a). It is estimated that roughly one-third of today's timber harvest comes from planted forests, compared to essentially a negligible portion 50 years ago (FAO 2001).

Once forests are planted, rather than being generated naturally, tree improvements using both traditional breeding techniques and bioengineering approaches become a viable option. Today, industrial forestry is moving on two fronts with tree improvements from traditional breeding techniques and with major research efforts oriented to the production and commercialization of transgenic trees.

Thus far, essentially all of the productivity increases in planted forests have resulted from species selection—traditional breeding approaches that have created superior high yield trees—and more intensive management. Regardless of the success

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[9] See Parkinson (1997) for an early discussion of some of the biopesticide possibilities.

of transgenics, plantation forests are likely to continue to displace traditional natural forest harvests. Sohngen et al. (1999b) estimate that by 2050, roughly 75–80 percent of the industrial wood harvested will originate in planted forests.

Potential Environmental Benefits

Forest Protection

One positive environmental implication of higher yielding forest plantations is that more industrial timber can be produced on less land. With forest growth and yield rates in the conservative range of what is currently possible for plantations in high-yield areas, all of the world's timber production could potentially be produced on an area roughly five to ten percent of the total forest today (Sedjo and Botkin 1997). The consequence of the increase in high-yield planted forests is that it will draw timber harvests away from natural and old-growth forests, allowing these forests to be used for nontimber purposes. This is more than a hypothetical possibility. Just look at the dramatic increase in planted forests in the past 50 years alone. Should transgenic trees play a major role in enhancing plantation timber productivity, the pressures to harvest in natural forests will continue to decline. The opportunity could arise whereby almost none of the globe's natural forest is pressured by timber harvests. More of the earth's forest could remain in their natural states, thereby maintaining continuous habitat for biodiversity conservation.[10]

A challenge of the middle part of the 21st century may be that of keeping adequate natural forested land in forest, since the financial incentive for maintaining natural forests for production would increasingly be absent.

Toxic Cleanup and Bioremediation

Genetic engineering can create transgenic trees with the ability to remove heavy metals and other toxics from contaminated soils in places where other forms of cleanup are prohibitively expensive (Rosner 2004, Bryson et al. 2004).

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[10] For a wide-ranging discussion of the potential of plantations to protect natural forests and the limitations see Friedman and Charnley (2004).

Recovering Damaged Species

In addition to benefits to the environment generally and to industrial wood production, gene transfer offers a potential means of recovering some of our lost natural forests. One hundred and fifty years ago the American chestnut was the dominant tree in many eastern hardwood forests. Unfortunately, an imported Asia fungus has eliminated the tree from the landscape. While the disease attacks the above ground portions of the tree, the underground roots have remained immune; hence living remnants of these trees remain. Fortuitously, the Chinese chestnut has genes that have made it resistant to the disease. Researchers are now working to transfer the resistant gene to the America chestnut with the view to its recovery (Bailey 1997). Thus, tree biotechnology offers a number of opportunities for achieving environmental goals including widespread recovery of certain trees from species threatening diseases.

6. Concerns About Transgenics

While the potential of plantation forests to reduce harvests on natural forests is becoming a reality, concerns about the implications of transgenics persist. These concerns usually fall into one of two categories: health and safety and environmental. The question of health and safety is would consuming the transgenic plant by humans or animals have any deleterious effects on their health. For forestry this is not a major issue, but rather the major concerns related to possible ecological damage that might be associated with the release of a transgenic tree into the environment.

Environmental Concerns

The problem areas for trees are largely environmental (Mullin and Bertrand 1998). These include concerns that a transgenic tree may directly become a type of invasive. Botkin (2001) has likened a transgenic to the introduction of an exotic, some of which have become invasive.[11] Another perceived problem is "gene escape." That is that the transferred gene might escape to a wild relative thereby increasing the fitness of

[11] However, other ecologists have argued that the risks associated with a transgenic becoming an invasive are generally lower and more predictable than for an exotic because the plant has only a couple of introduced genes and the general expression of these are known. Thus the expression or any problems associated with transgenics should be easier to identify than the effects of exotics with large numbers of unknown genes.

that relative and enhancing its ability to significantly disrupt the existing ecosystem (DiFazio et al. 1999). It is this set of concerns, in addition those about the health and safety of foods, that has resulted in most countries requiring the automatic regulation of a transgenic plant and that for commercialization the plant, including trees, must successfully pass through a deregulation process, which assesses the risks of any adverse or damaging environmental effects that could be associated with their common use.

Trees, being perennials, differ from most transgenic plants, which are annuals. They also tend to have long lives and delayed flowering, which further complicates their assessment compared with transgenic annual plants. I should note, however, that trees are not the only long-lived transgenic plants. Other long-lived transgenic plants include grasses. Delayed flowering generally makes the examination of the impacts of the introduced genes over generations more difficult, but not impossible, since certain tissue cultural approaches, grafting, and other techniques may be helpful in reducing the intergenerational delays. Nevertheless, regulatory complexities are likely to persist.

Gene Escape

A fundamental concern in the tree genetic engineering is on the question of what is known as gene escape or gene flow. In addition to the question if gene flow will occur is whether the flow will persist and whether will it be detrimental. In the absence of containment or remedial actions there is a broad consensus that some degree of gene flow will almost certainly occur. Pollen will be transported, seed may be released, and with some plants, including some tree species, vegetative propagation may occur. Should gene flow happen, the issue is whether the transfer of genes to other plants could cause damages to either other domesticated plants or, perhaps more importantly, to the wild plants existing in the natural ecosystem, particularly if the wild plants are of a similar species.[12] A principal concern with transgenics in forestry is that the introduction of an exotic gene in a transgenic may be passed from the plantation forest to trees in adjacent stands. For example, anxiety has been expressed over the risk of transgenic forest tree invasiveness at the interface of private forests and public lands (Williams 2004). Also, an area of concern with crops is that the transfer of a gene from

[12] One example of this potential problem for food crops is concern that an escaped gene might despoil a pristine species collection and thereby compromise its usefulness for developing improved hybrids of a particular plant, such as corn.

transgenic crops to nontransgenic crops could disqualify the "tainted" crop from nontransgenic status and hence preclude it from sale in certain markets, for example the European Union.[13] This effect might apply to tree nurseries also.

The general issue with gene flow is that of "flow versus fate." Given that gene flow will occur, under what circumstances will it be deleterious to a planted forest or to the natural environment, and what are the approaches that may be undertaken to contain or mitigate these effects?

It is generally agreed that traits that impart increased fitness will persist. Fitness is defined as the relative success with which a genotype transmits its genes to the next generation. Major components of fitness are survival and vegetative growth in perennials and reproduction through pollen and seeds. As noted, individual transgenes can have positive, neutral, or negative effects on fitness. There is the question of whether a specific genetic change that enhances a desired commercial trait is likely to enhance the tree's fitness in the wild. Often, there are fitness costs associated with domestication and with transgenics. These costs are often found in reduced rates of reproduction and generally have negative effects on survival. In many, perhaps most, cases traits desired by humans enhance the production of a feature desired by humans—such as cellulose production, lignin extraction, and tree form—do not enhance tree fitness in the wild. However, according to Snow (2003), transgenic traits do not provide fitness but that are not deleterious to survival are still likely to persist in wild populations. This could be the case for a number of introduced traits. However, in the absence of enhancing fitness in the wild, there is little reason to expect that the transgenic tree is likely to become a pest or significantly modify the ecosystem. So the persistence of transferred genes, per se, need not generate damages or disruptions.

Limiting Gene Escape

The question remains, however, of how to treat modifications that enhance the fitness, vitality, and survivability of the plant in the wild. One approach is formal containment, which is often required in trial research plots. Other techniques are under consideration or development. A common anticipated approach for addressing the problem of gene escape is that of minimizing or eliminating the tree's ability to transfer genes through modifications that delay or prevent (terminate) flowering, thereby

[13] One nonbiological type of damage would be if a non-GMO crop were tainted with a transgenic gene, when markets were reacting negatively to transgenic crops (as in the European Union).

promoting actual or de facto sterile trees (Meilan et al. 2004, Kellison 2004).[14] This is a common area of bioengineering tree research and is likely to be a precondition, at least in the United States, of the deregulation of transgenic trees. In agriculture sterilization approaches have been contentious and related to property rights issues and the potential use of the improved seed for the next planting without payment to the developer. In forestry, with its long growth periods, the property rights aspect is unlikely to be important since the technology is likely to be obsolete before reproduction could be undertaken.

Another method for containing the gene flow is to avoid locations where there are compatible wild or weedy relatives in the natural environment. An advantage of planting a transgenic that is an exotic species is that close relatives are usually absent making the probability of gene transfer nonexistent. For example, pine is not indigenous to South America so the problem of a gene transfer from a planted pine to a native tree is nonexistent (DiFazio et al. 1999).[15]

A particular concern in forestry is with the effect of Bt genes that impart pest resistance properties to planted trees and which, under some circumstances, could impart these properties to wild trees. In this case there is a concern that escape of the Bt gene would provide the recipient plant with enhanced fitness that could disrupt the competitive balance in the natural system. At this point in time, in the case of trees, there appears to be little if any research proceeding on the development of Bt genes for trees.[16]

Bioconfinement

To address some of the potential problems identified above, some GE organisms will require bioconfinement during their field-testing phases. The National Academies of Science (2004) point out that many crops pose little hazard because the traits that make them useful to humans also reduce their ability to establish feral population in

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[14] Terminator genes are some used in annual crops to prevent seed of the transgenic from being used for future planting. For trees, however, this is unlikely to be a serious problem since the time required for a viable seed is sufficiently long as to probably render the embodied technology largely obsolete for future plantings.

[15] South America is particularly attractive location for planted forest since most of the planted trees are exotics, such as, pine or eucalyptus, and thus the problem of gene escape is largely absent.

[16] This author finds little evidence of any research in the development of Bt genes for trees in the United States or Canada. Of course, this need not be true worldwide.

agricultural or nonagricultural habitats. However, if some transgenics should confer the ability to overcome factors that limit wild populations, significant invasive problems could ensue. In addition to rendering plants sterile, other methods include targeting pollen to confine pollen-mediated gene flow. The National Academies report also states that although the efficacy of some of these approaches is known, most are untested.

Sterility is particularly attractive for trees because transgenic escape is not possible for sterile plants, because they do not produce fertile pollen or seeds. Furthermore, since the stem or trunk is usually the important output of the forest tree, the loss of the seed is not significant.[17] However, the degree of sterility may vary by plant and by environmental condition and often may not be complete. Also, there are concerns about maintaining long-term stability of the sterility trait.

Many dioecious (unisexual) plants, including many deciduous trees, can be propagated vegetatively. For such plants confinement could be achieved if such trees were grown in unisexual stands far from wild relatives.

Environmental Impacts: A Summary

The question arises, then, can plants with transgenic traits that provide positive effects on fitness be released into the wild without potentially creating negative ecological impacts? The consensus response among scientists appears to be "it depends" (Snow 2003). Most escaped genes are unlikely to enhance fitness in the wild and thus unlikely to have negative impacts, especially over the long term. For example, example, the escape of a herbicide-resistant gene into trees in the natural environment provides these trees with herbicide protection against a specific herbicide. However, in most cases these trees are unlikely to be subject to attempts to control them through herbicides. Furthermore, alternative herbicides are available in the short term and over longer periods the common herbicides will undoubtedly be modified. This type of argument, however, cannot be made for a Bt gene that protects against certain local pests. In that case the fitness advantage is likely to persist through time, so other approaches would be needed to avoid the chances of the persistence of the trait.

Additionally, there are a host of confinement techniques. These include physical confinements for field trials, confinement of certain transgenics to regions where no

[17] Given the longevity of a tree and the tree improvements through time, the genetic improvements embodied in the seed at maturity are likely to be obsolete.

related wild genus occur, such as pine in South America, to various terminator and sterility techniques that could be applied to deregulated commercialized trees.

7. Regulation of Transgenic Trees

U.S. Regulatory Framework

A consistent principle of health and environmental law in the United States is that products introduced into commerce should either be safe or present no unreasonable risk to humans or the environment. How this principle is applied varies, depending on which law applies, which agency has jurisdiction, and the social perception of risk.

Products of biotechnology do not always fit comfortably within the lines the law has drawn, which are based on the historical function and intended use of products. The relationship and coordination of the various authorities is governed by the policy statements contained in the 1986 Coordinated Framework for the Regulation of Biotechnology (51 *Fed. Reg*. 23302; June 26, 1986) and the 1992 Policy on Planned Introductions of Biotechnology Products into the Environment (57 *Fed. Reg.* 6753; Feb. 27, 1992), which was designed to provide for a coordinated regulatory approach to be adopted by federal agencies. Products of biotechnology are regulated according to their intended use, with some products being regulated under more than one agency.

Three main agencies are involved in regulating transgenics. The Food and Drug Administration (FDA) of USDA is concerned with food safety. EPA regulates toxics and pesticides under the Toxic Substances Control Act of 1976 (TSCA) and the Federal Insecticide, Fungicide, and Rodenticide Act of 1996 (FIFRA) and overall environmental safety under the NEPA. For USDA, APHIS determines whether a gene-altered plant, crop, or tree is likely to be a plant pest that could harm U.S. agriculture under the PPA (especially Title 7 U.S.C. Sections 7701 *et seq.*).

The 1986 Framework identified two laws containing requirement applicable to all agencies reviewing biotechnology products. The NEPA was a precursor to EPA and later overseen by that agency—and the Endangered Species Act of 1973. In its role overseeing the NEPA, EPA has broad powers and requires that federal agencies publicly address any impact of their activities that may significantly affect the environment. The detailed statement required is referred to as an environmental impact statement (EIS) and is typically preceded by a rough environmental assessment, to determine whether a full-fledged EIS is necessary (Bryson et al. 2001).

Separate from questions about human health and safety is whether a gene-altered plant, crop, or tree is likely to be a plant pest that could harm U.S. agriculture. This question is examined by APHIS under the PPA, (especially Title 7 U.S.C. Sections 7701 *et seq*.). This act is the new statutory authority under which APHIS regulates genetically engineered organisms. This authority supersedes their authority under some of the earlier acts such as the Federal Plant Pest Act, which mandates monitoring of plants that offer potential pest risks. In particular, the PPA includes a broader definition of a noxious weed to include plants (previously the definition was limited to nonnative plants). It is under this broader definition that APHIS regulates GMOs. The PPA is generally applied to all genetically modified plants, including trees (Bryson et al. 2001, 2004).

The PPA consolidated and enhanced USDA's authority to prohibit or restrict the importation, entry, exportation, or movement in interstate commerce of any plant, plant product, biological control organism, noxious weed, article, or means of conveyance if the Secretary determined that the prohibition or restriction is necessary to prevent the introduction into the United States or the dissemination of a plant pest or noxious weed with the United States. (7 U.S.C. 7712(a)).

The Deregulation Process

The implementation of the assessment related to transgenic plants is centered on determining the health, safety and environmental implications of the modified plant. The risk criterion is that the new varieties are determined to be as safe to use as are varieties modified by traditional breeding techniques, which do not require deregulation.

A regulated article is defined as "any organism which has been altered or produced through genetic engineering of the donor organism, recipient organism, or vector, or vector agent belongs to any genera or taxa designated in the regulation (provision 340.2) and meets the definition of a plant pest or any organism or product which APHIS determines or has reason to believe is a plant pest (7 CEF 340.1). Regulated status has been applied to most of the genetically engineered plants that have been developed to date (Bryson et al. 2001).

The deregulation approach can be briefly summarized as follows: *permitting, notification*, and *petition*. For regulated articles, such as transgenic plants, a *permit* must be obtained from APHIS for the importation, interstate movement, or release of the article into the environment. To achieve deregulation requires field testing. When undertaking field testing, *notification* of APHIS that it is about to begin is required. Upon completion of field testing and other relevant procedures, breeders may submit a *petition* for deregulation to APHIS. The petition details the field testing results, provides a comprehensive literature review together with any other relevant information and experience. Upon receipt and evaluation of the petition, APHIS, using a scientific committee, makes a determination of whether to deregulate. Once a "determination of nonregulation status" is made, the product and its offspring no longer require APHIS authorization for transport, release, or communication in the United States. In the petition process, the general approach appears to be for APHIS to work cooperatively with the developer. Petitions are seldom rejected outright but they are not uncommonly returned as being incomplete or providing insufficient information.

The overall assessment by APHIS includes a consideration of the potential effects on the wider environment to ensure that any environmental impacts are not likely to be significant. Broader environmental considerations are mandated under NEPA (Title 42, U.S.C. sections 4321 *et seq.*). In addition, EPA is directly involved in the deregulation process for any transgenic plant that has pesticidal or toxic properties under the TSCA and the FIFRA, as well as for overall environmental safety under the NEPA.

Some Deregulation Specifics

Genetically modified trees are expected to be tested in the greenhouse and then in highly monitored experimental field releases before deregulation and widespread commercialization (Beardmore forthcoming).

Field Testing

Implementation of PPA related to transgenics is centered on assessing the safety and environmental implications of the modified plant. Field tests are one of the major sources of information.[18] They are usually undertaken by the developer and occur

[18] The first field release of a transgenic forest tree was in Belgium in 1988, however, today most forest tree trials are in the United States. The first U.S. field trial was in 1993 (Beardmore forthcoming).

under controlled conditions for most genetically engineered organisms, particularly new or genetically modified plant varieties. Consistent with the basic criterion, they are designed to demonstrate that the transgenic variety is as safe to use as traditional varieties.

Under authorities provided by the PPA, APHIS issues field-test permits for new plants that have the potential to create pest problems in domestic agriculture. This could apply to plants, plant products and other articles developed through biotechnological processes if such plants, plant products, or articles present a risk of plant pest introduction, spread, or establishment. The APHIS regulation specifically applicable to genetically modified organisms was first promulgated in 1987 and controlled the introduction of a class of organisms referred to as "regulated articles" (Bryson et al. 2001).

To obtain a permit for field-testing, a plant breeder must provide detailed information, including scientific details relating to the development and identity of the regulated article, the purposes for introduction of the regulated article, and the procedures, processes, and safeguards that will be employed to prevent escape and dissemination of the regulated article.

Notification

The plant breeder may field-test a plant that meets the eligibility criteria by simply submitting a notification letter to APHIS and by meeting certain performance standards. The eligibility criteria require, among other things, that the genetic material be "stably integrated" in the plant genome, that the function of the genetic material is known and its expression does not result in plant disease, that it does not produce an infectious entity or will not be toxic to nontarget organisms, and that it has not been modified to contain certain genetic materials from animal or human pathogens. The performance standards also include controls on shipment, storage, planting, identification, and conduct and termination of the field trial.

Petitioning

If testing demonstrates that the organism is not a plant risk, an APHIS assessment will consider that data and information that, with the exception of the deliberately introduced gene, the genetically engineered line is the same as a nonengineered parental line with respect to a suite of traits. If this is the case and there is sufficient familiarity with the introduced trait, the recipient plant, and the environment, APHIS can determine with a high degree of confidence that the engineered plant meets the criterion of being no more likely to become a plant pest than a traditionally bred plant. Once a determination of nonregulated status is made, the new plant variety may be developed further through traditional breeding. It may be produced, marketed, distributed, and grown without any other special oversight on the part of APHIS. Nonregulated status permits unencumbered commercialization.

Risk Assessment

Environmental assessments require the following steps: 1) identifying hazards, 2) assessing actual risks that may arise from a hazard, 3) determining how risk can be managed and whether to proceed with the proposed action, and 4) comparing the risk with those posed by actions involving comparable organisms.

In conducting risks assessments, APHIS begins with consideration of the existing knowledge base and of the traditional procedures that are used in developing any new crop variety. This baseline enables APHIS to identify hazards and then determine whether the risk posed is significantly different from those well-known risks that are identified established practice. This process, which is referred to as "familiarity," is based on the philosophy that the types of safety issues raised by genetically engineered plants are no different from those for traditional breeding when similar traits are being conferred. However, the magnitude of a particular risk may differ. The extensive experience gained from traditional plant breeding provides useful information in establishing parallel risk associations for newly developed crops.

For plants, familiarity takes account of knowledge and experience with the:

- particular crop, including its flowering/reproductive characteristics, ecological requirements, and past breeding experience;
- agricultural and surrounding environment of the trial site;
- specific traits transferred to the plant;
- results of previous research;
- scale-up of the plant crop varieties developed by more traditional techniques;
- scale-up of other plant lines developed by the same technique;
- presence of related and sexually compatible plants in the surrounding natural environment and knowledge of the potential for gene transfer between the plant and the relatives; and

- interactions among the crop plant, the environment and the trait.[19]

Taking these factors into account, familiarity can range from very high to very low. The standard has been that for a GE crop to be commercialized in the United States, there must be a high degree of familiarity (Bryson et al. 2001).

Major modifications or hazards that have been identified for which risks are assessed include the following:

- plant pathogenic potential of the transgenic, for example, the ability to harm other plants;
- potential to negatively affect handling, processing, and storage of commodities containing the genetically engineered plant;
- changes in cultivation that might accompany adoption of the transgenic;
- potential harm to nontarget organisms;
- changes in the potential of the genetically engineered plant to become a weed;
- potential to affect weediness of sexually compatible plants;
- potential impacts on biodiversity.

Special Concerns Regarding Trees

Special concerns have been expressed with respect to largely undomesticated species of forest trees due to the fact that they usually have a longer life span than other plant species. APHIS has noted that field trials of many species of trees can be safely preformed over a period of several years under the notification procedures since trees do not become sexually mature for a considerable and well-established period of years. Moreover, tree species can be effectively isolated from wild population by the appropriate choice of test location, by the use of physical methods for confinement of pollen, or through the application of various sterility approaches.

Nevertheless, APHIS acknowledged that long-term vigilance is required. Because field test involving trees may be of several years duration and could involve unexpected exposures of nontarget organisms, continual adherence to performance standards must be maintained. Moreover, procedures used to ensure reproductive confinement during the first years of a field trial may not be adequate at a later time in

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[19] See Organization for Economic Cooperation and Development. *Field Releases of Transgenics Plants, 1986-1992, An Analysis* (1993).

the trial. For that reason APHIS requires that all field trials under notification for more than one year be renewed annually (Bryson et al. 2001).

As the regulatory structure suggests, the primary reason for regulation of transgenics is the potential for health, safety, or environmental risks. The issues related to transgenic trees are somewhat different from those of much of agriculture. Traditional health and safety issues related to food ingestion are largely absent with wood fiber (although cellulose is sometimes used as a food filler). The area of concern for trees is largely environmental (Mullin and Bertrand 1998): regulators must initially presume that transgenics pose new risks of environmental damages.

8. APHIS Performance

Deregulation, as noted, is based on assessment of the results of field tests, statistical analyses, literature review, and so forth. AHPIS reviews about 1,000 applications for field-testing transgenics each year. Only about 61 transgenics, representing 13 species have been deregulated over the past 20 years. In no instance has any biotech plant approved for field testing by USDA created an environmental hazard or exhibited any unpredictable or unusual behavior compared to similar crops modified using traditional breeding methods (Subcommittee on Basic Research 2000).

APHIS has received around 100 petitions for deregulations of genetically modified crops and has overseen several thousand field trials (NAS 2002). To date, most of the field tests have been agricultural crops; as of 2000 only 124 field tests of genetically altered trees have been authorized (McLean and Charest 2000), including transgenic spruce, pine, poplar, walnut, citrus, cherry, apple, pear, plum, papaya and persimmon. Only one tree, a papaya, has achieved deregulated status.

Tree Deregulation

Trees make up only a small portion of the plants tested. However, the number of trees tested has increased dramatically in recent years, as has the total number of plants of all types.

Trees can be classified as orchard, ornamental, and wood or timber. The experience with timber trees is presented in Table 5. From 1987 to 2001, timber trees were involved in only 1.2 percent of the total number of field tests, for both agricultural and forest crops, and 91 percent of those occurred in the latest reported period (1997–2001). A total of 90 timber tree field tests were undertaken representing four tree genera between 1987 and 2001, with the poplar genus being involved in well over one-half of the trials. The number of trees tested has increased dramatically in recent years. About 57 percent of the trees tested are timber trees.

Table 5. Field Tests for Transgenic Timber Trees, 1987–2001

Years	Poplar	Pine	Walnut	Cotton-wood	Total tree tests	Total APHIS-approved crop tests	Percentage timber trees of total crop tests
1987–1991	1	0	2	0	3	181	1.7
1992–1996	3	0	2	0	5	2,354	0.2
1997–2001	52	15	8	7	82	4,804	1.7
Total	*56*	*15*	*12*	*7*	*90*	*7,339*	*1.2*

Source: Information Systems for Biotechnology. (www.isb.vt.edu/cfdocs/fieldtests1.cfm, accessed October 28, 2004.)

Table 6 provides information about duration and size of the trials. The average tests have lasted from one to almost seven years on fields, with the field size per test ranging between 0.25 and 2.6 acres.

Table 6. Characteristics of APHIS-Approved Transgenic Tree Trials

Tree	APHIS-approved tests, 1987 to July 2002	Average duration (months)	Average size (acres)
Poplar	65	14	1.5
Pine	17	56	0.25
Walnut	12	55	1.9
Cottonwood	7	45	2.6

Source: Information Systems for Biotechnology (www.isb.vt.edu).

The United States accounts for an estimated 61 percent of worldwide tree trials. Other countries undertaking field trials include Australia, Canada, Chile, France, Italy, Japan, New Zealand, and South Africa.

Despite the increase in field-testing in recent years, however, only one petition for deregulation of a tree has been submitted and granted—the fruit tree papaya.

Orchards in Hawaii were experiencing severe disease problems (see case study below), and a genetic modification was developed to impart disease resistance. This transgenic papaya was deregulated and is now in widespread use in Hawaii. No other trees of any type appear ready for imminent deregulation: APHIS has received no petitions for the deregulation of a transgenic timber tree. Worldwide, there are no documented transgenic timber trees that have been commercially released, although there are rumors that transgenic trees are being planted commercially in China.[20]

Case Study: Papaya

The experience of the sole APHIS deregulated tree, the papaya, is instructive and provides insights into the types of problems transgenics can address, the process of deregulation, and some of the difficulties likely to be encountered in the deregulation of trees in the future.

In the 1940s, the papaya crop in Oahu was devastated by the new, insect-borne papaya ring spot virus (PRSV). In a mature plant, it causes the leaves to begin to wilt, and the fruit to have little sugar and mottled skins. Young plants that had contracted the disease died. The virus spread slowly until all of the papaya orchards were infected. To escape PRSV, the papaya industry moved to the island of Hawaii, but by the 1970s the virus had followed. Plant breeders crossed wild papaya with commercial species and achieved resistance, but the fruit was of low quality.

The technology for a disease-resistant papaya was developed by Dennis Gonsalves of Cornell University, in cooperation with researchers in Hawaii. The team used a viral coated protein, developed from other plants (watermelon, cucumber, zucchini, and winter squashes). They inserted the viral genes into the papaya and created a strain that was resistant to PRSV. The team had discovered a natural plant mechanism that recognized the messages from foreign DNA to protect foreign protein and destroyed those messages before the protein could be made. The gene inserted into the transgenic papaya set this immunity mechanism into play.

In 1994 a larger field trial was started that proved very successful. Control plants all became infected within 11 months, but after 35 months the transgenic plants

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[20] At a November 2004 meeting of the FAO Panel on Forest Genetic Resources, a principal research scientist of the Chinese Institute of Forestry reported on the establishment of close to 300 hectares of transgenic poplar in China; personal communication with Yousry El-Kassaby (January 20, 2004).

remained healthy (Pew 2002). Subsequently the disease-resistant papaya was approved by APHIS as it was determined that it met the requirements for deregulation. However, the actual planting of the trees was prevented because the developers needed to gain approval for the various patented technologies that had been used in the creation of the disease-resistant tree. If someone uses these technologies in a commercial product without the approval of the patent owner, the user is subject to an injunction preventing the application of the technology and also is possibly liable for damages, or both. In this case the legal use of the patents for the transgenic papaya was provided gratis by the various patent holders, since the innovation had limited applicability and was viewed as socially desirable. Most of the papaya growers are in small family-run operations. The legal background and activities necessary to obtain legal use of the patents are discussed in Goldman (2003). However, for more commercially viable operations, the purchase of the rights to utilize patents required for the development of a transgenic tree could be both costly and time consuming.

9. Regulatory Issues

Risk and Coverage

The U.S. Approach

Two major issues in the regulation of plants are the level of acceptable risk and the types of plants covered. That is, should the regulation apply on the basis of the genetic modification process or on the basis of attributes of the plant that may pose risks? The formal U.S. decision criterion is that the product presents “no significant or unreasonable adverse risks.” Note that some “reasonable risk” is allowed. Currently, under the U.S. approach, all transgenic plants and trees are automatically classified as regulated articles that must go through the deregulation process to be eligible for commercialization. Alternatively expressed, any plant that involves the insert of a gene using a nonsexual approach is defined as a transgenic and is automatically regulated.

Some biologists have argued that regulation would better be applied to plants on the basis of the plant attributes, rather than simply on the basis of the genetic engineering process. The decision would be based on the “novelty” of the plant independent of the process used in its development. This criterion would be applied, in principle, to all novel plants, whether the modification occurred by traditional breeding or genetic engineering.

Approaches of Some Other Countries

The argument of those suggesting regulatory change is that the transgenic process does not inherently lead to more risky products. Rather, they say, regulators should focus on the changes and the attributes, whether generated by traditional or transgenic approaches, which could present a social or environmental risk. That is, the risks are associated with particular attributes, and it is the products with these attributes that ought to be regulated. This is the approach used in Canada, which applies the novelty criterion to both traditionally modified and genetically engineered varieties. However, thus far in Canada, no tree modified by traditional methods has yet been required to go through formal deregulation, whereas almost all transgenic plants and trees require deregulation (McDonald 2003).

Another approach is the one used in China, which has a risk scale that ranges from no risk to low, medium, and high risk. A preliminary appraisal places a new plant in one of these categories. Those in the no-risk or low-risk classes are automatically deregulated; those given a higher risk rating go through a more extensive deregulation protocol.

The European Union's decision criteria are particularly averse to risk and require that GM plants present no additional or increased risks—that is, zero risk. This is stricter than the U.S. and Canadian standards, which accept some level of risk.

Although most countries agree on the need for some type of risk assessment for transgenic plants, there is as yet no global consensus on the degree of potential harm that will be tolerated and the degree of severity of the risk (Pachico 2003).

In summary, the formal decision criteria regarding the level of acceptable risk vary by country, from zero risk in the European Union to reasonable, low, and acceptable risk in other countries. The formal criteria of the United States, China, and the European Union focus regulation on transgenics. Only Canada seeks to regulate on the basis of the novelty of new plants, however those new attributes have been achieved, but in effect, only transgenic plants have been regulated.

Conditional Release

Another outstanding issue is the question of conditional release. Under the current system, a plant is either regulated or non-regulated. The concept of conditional release would allow conditional release that would enable the developers to answer questions related to the development and us of a GMO prior to its unconditional release. The purpose of conditional release would be to allow movement towards unconditional release in a step-by-step process. Restrictive conditions could be altered as the relevant evidence becomes available. According to USDA, revisions in the area of conditional release are under consideration (USDA News Release 2004).

10. Attitudes toward Transgenic Trees and Regulations

In this section I characterize the attitudes of various groups—including tree growers, tree processors, tree developers, direct and indirect consumers of forest products, and environmentalists—toward transgenic trees and the regulatory structure. These characterizations are not based on scientific sampling procedures but rather reflect my impressions based on conversations with members of the various groups. Not surprisingly, attitudes toward transgenic trees vary substantially among these groups and, as has been shown in various surveys of attitudes towards transgenic foods (Pew 2003b), also vary considerably across countries.

Tree Breeders and Developers

As might be expected, among transgenic tree developers, whether in the private sector or public, the attitude toward transgenics is basically positive. These groups generally believe that there is a place for some type of regulation, but criticize the U.S. approach of requiring all transgenics to go through the deregulation process. A common view among research biologists is that for certain types of predictable transgenic changes, a formal deregulation approach is not required. Such an approach would, obviously, require some preliminary assessment to determine which transgenics require a more comprehensive assessment.

Tree Planters and Growers

Although many forest-based firms engage in tree improvement and some conduct research to improve cloning techniques, especially for pine, few are directly engaged in tree genetic engineering research and development. In the industry structure that has emerged in the past decade in North America, work on transgenics is undertaken largely by universities and specialized research firms. Most firms no longer conduct work on transgenics as part of their overall tree improvement programs. There are almost surely economies of scale in concentrating research efforts in a few places rather than fragmenting the efforts.

Another explanation is, at least in part, the desire of forest-based firms to distance themselves from the activity of genetic engineering during the current period of questionable public acceptance. Transgenics are attractive in concept because they present opportunities to reduce costs and increase productivity, but tree growers are very sensitive to actual and expected behavior of markets and, given the controversies over genetically modified products, are somewhat wary.

Environmentalists

A random inquiry at the September 2003 World Forestry Congress in Quebec City found a range of views among environmentalists from extremely hostile to skeptical toward transgenic trees. Representatives of "green" organizations, such as Greenpeace, exhibited great hostility and made ominous predictions of how transgenic trees would damage the natural environment. The guidelines of Forest Stewardship Council, a certifier of acceptable forestry practices, specifically prohibit the certification of forests of transgenic trees. At the other end of the spectrum are organizations, such as the Nature Conservancy, that have no institutional position on transgenics. In conversations, some staff professionals acknowledge that transgenic trees may have some role in forestry's future. They note, however, that this issue is generally out of the mainstream of their organization's direct concerns. However, some individuals with generally negative views toward transgenic were neutral to positive in their reaction to benefits, such as the restoration of the American chestnut, that might be provided to the natural environment through genetic modification.

Consumers

Industrial consumers of wood products—those for whom wood is an input to production, such as pulp mills—are generally enthusiastic about transgenic trees with certain characteristics that improve the economics of production and/or improve ensuing products. Trees with more fiber, less juvenile wood (which is low in cellulose), and less or more easily removable lignin will reduce processing costs and are therefore, in principle, desirable. The proviso is that such products must be acceptable to consumers.

The attitudes of consumers about final products—paper, lumber, panels—made from transgenic wood are problematic. Although transgenic wood products are unlikely to be in markets for another 20–30 years, the anticipated attitude of consumers is important for developers. Without an expectation of a viable market, the developments and investments are unlikely to be forthcoming. As with food crops, in many cases genetically modified products could be better in quality or lower in cost, or both. And wood products have the added benefit that wood generally involves no food safety issues. Thus, the extent to which retail consumers might resist transgenic wood products would appear to depend largely on whether they have environmental or philosophical concerns. The experience with certified and ecolabeled wood products offers some insights: although there is little evidence that consumers are willing to pay a price premium for certified wood, some firms find that certification imparts a competitive advantage, even if not a price advantage (Sedjo and Swallow 2001). How these attitudes may translate to a transgenic wood market remains to be determined.

11. The Biotech Industry

The transgenic tree industry comprises several types of organizations: universities, biotech firms, conventional tree-improvement program delivery systems, and forest based companies. As in agriculture, conventional tree-breeding programs gradually incorporated biotechnology and transgenic techniques, including those first used in agriculture. For example, Monsanto, an early leader in the biotech industry known primarily for its innovations in crops, developed technologies that also have applications for trees (Sedjo 2001) and has, in the past, worked on creating low-cost means to introduce herbicide-resistant genes into trees.

Until recently, many of the large North American forest-products companies conducted transgenic research, in some cases in collaboration with a major biotech gene developer, such as Monsanto; the results could then be introduced into a forest company's improved tree lines. Today, however, most research on the application of herbicide resistance in trees appears to be undertaken by universities; the tree improvement research programs of most firms apply traditional tree-breeding techniques.

Recently, several forest products firms have formed a joint company, ArborGen, which specializes in the development of transgenic genes and techniques for the participating firms, and perhaps for the market more generally. Considerable research effort is directed to increasing and improving wood fiber and its utilization through modifications that will, for example, reduce the costs of extracting lignin from the wood in the pulping process. Meanwhile, the forest-based firms are typically continuing their traditional breeding programs, but not their genetic engineering research, with the view to eventually introducing the selected genes into the individual company's elite seed stock.

Clonal Development

Plantation forestry depends on the development of elite planting stock that can consist of seedlings or materials appropriate for vegetative propagation. The procedure for obtaining seedlings, particularly in conifer, is through a seed orchard program where the improved trees are cross-pollinated to produce improved seed, which are mass produced into seedlings for planting. Although this approach is common, it has the disadvantage of diluting the desired trait since both parents are genetically represented in the seedling due to gene segregation during meiosis and the presence of a significant cross-pollination from unimproved trees outside the orchard population.

The other approach is that of vegetative or clonal propagation. Vegetative propagation has been practiced for centuries in many plants, including grapes, potatoes, and many deciduous trees. The simple form of vegetative propagation involves cuttings from a plant, such as a branch or root, which are planted. Fences consisting of live trees, common in much of the tropics, are created in this fashion. When vegetatively regenerated, the plant is a clone, having the same genetic composition as the original plant.

Cuttings and propagules (rooted plantlets from tissue culture, embryogenesis, and so on) are the planting stock for clones. The development of clonal trees typically takes the following form. First, trees with superior traits are developed through traditional breeding approaches. For trees that can propagate vegetatively, generally deciduous trees, cuttings from the most outstanding parent trees (ortets) provide clonal material, cuttings, for planting. The clonal approach has the advantage of capturing all the genetic superiority for the donor plant because the process relies on mitosis cell division that does not impart any gene segregation. This is unlike sexual reproduction that relies on meiosis and hence some dilution of the positive attributes due to gene segregation. Also, the cost of the cuttings tends to be modest thereby reducing plantation establishment costs. The rooted plantlets can be planted en masse and the beneficial traits of the single tree duplicated in each new tree.

This approach has commonly been used for poplar, eucalyptus, and other deciduous trees. Vegetative propagation, however, has not been an effective technique for most conifers—a biological family in which vegetative propagation is extremely rare. Thus, for conifers, the elite trees are typically developed using various vegetative reproduction techniques involving the manipulation of plant tissue that ultimately allows for vegetative reproduction of the whole plant. Tissue culture broadly refers to clonal techniques of growing plant tissue or parts in a nutrient medium. Embryos from superior trees are then manipulated to create multiple clones of the superior tree in the form of rooted plantlets. The reproduced materials, propagules, become the material that then is planted to become a clonal tree.

Various approaches of replicating conifer materials are now under development, with the view to achieving mass propagation at low cost. As with vegetative propagation, an advantage of cloning is that all of the genetic gain in an improved tree can be captured without dilution. This approach allows for large scale planting of plantlets with the desired genetic makeup.

It should be noted that sophisticated cloning is not genetic engineering, it does not transfer genes asexually, and such activities are not regulated and do not require that a plant be deregulated. Even in the absence of any genetic engineering, however, the technique would allow the forest industry to take more complete advantage of traditional tree-breeding improvements.

While cloning provides distinct growing advantages in itself, a cloning approach also provides an excellent platform for the application of genetic engineering. Cloning can be viewed as an enabling technology that will facilitate the transgenic transformation of conifer trees. Through the cloning process the selected genes that have been inserted into a particular plant to create a transgenic can subsequently be transferred to produce transgenic propagules en masse, each one of which is identical and has the same externally introduced genes. It is generally recognized that to introduce transgenic conifer trees on a commercial scale will require an efficient low-cost approach to reproducing transgenic clones.

The ideal transgenic plantation technology would also include a cryopreservation ability, that is, the ability to preserve in a frozen state, a set of potentially productive clones for a period of years. Those identified in field tests as the most productive could subsequently be planted en masse. Where the clones are a platform for transgenics, the most productive will ultimately be chosen from these clones, after the transgenic innovation has been assessed and deregulated. The procedure involves propagation of young trees produced from tissue culture propagules. Genetic testing and field-testing must be done to determine which of the clones are best. If portions of each of the propagules are preserved in freezers until the best material is determined, the desired material can be removed from the freezers and used to mass-produce the desired seedlings.

A leader in the development of conifer clones is Cellfor, which is developing a technology and production procedures designed to allow it to produce low-cost clones, particularly of pine. With low-cost cloning techniques, the firm could clone elite materials developed using traditional breeding methods by forest products companies for the company's own use. Development of low-cost pine cloning techniques and procedures would also provide a platform for the low-cost replication of transgenic clones for large-scale commercial operations. It would be an "enabling" technology for the commercialization of transgenic conifer trees. Currently, there are still substantial hurdles before low cost conifer clones become generally available.

12. Issues for Tree Developers

Regulatory Procedures

Participants in the regulatory process generally agree that the existing APHIS procedures provide the basis for deregulation of transgenic trees but that the specific protocol needs to be worked out. This understanding was reflected in the meetings in July 2003 organized by APHIS to consider the regulatory problems unique to transgenic trees. The question remains as to whether regulation should focus on the process, transgenics, or on the attributes of the plant, irrespective of the process. Also discussed was the requirement that each gene must be separately field-tested. Developers are hoping to test several genes in one trial, an approach that would probably require some change in the existing regulatory protocol.

The longevity of trees makes monitoring for potential problems more difficult than with annual plants. Most tree improvement programs try to identify superior trees early in the cycle, so that the superior stock can be deployed quickly, but surprises in the tree's performance may appear as it approaches maturity. There is a fair degree of support in the industry for a conditional deregulation by APHIS, whereby distribution would be limited and monitoring continues until any outstanding uncertainties are resolved.

Costs of Deregulation

The costs of deregulation are high and affect decisions about the types of transgenic traits to develop (or avoid). These costs create an incentive to focus on traditional breeding, which requires no deregulation, even though the development costs can, in some cases, be greater than with transgenics. The biotech industry (Hinchee 2003) estimates that the costs of deregulation account for roughly one-third of the total development costs but are highly variable and uncertain. The uncertainty is not so much in the regulation per se but in the time and costs of achieving deregulation. When a transgenic plant gets to a certain stage, its developers can be confident about clearing the remaining obstacles of the deregulation process. But at the outset, they cannot know how many tests will need to be undertaken to demonstrate to the regulators that deregulation is justified.

The costs of deregulation increase if more than one agency is involved. APHIS has responsibility for all transgenic plants, but if a transgenic plant has pesticidal properties, such as a Bt gene, EPA becomes involved as well. Going through the process with two agencies undoubtedly raises the costs to the developer, perhaps very substantially. An emerging strategy appears to be to undertake developments that will be assessed by only one agency, APHIS, thereby reducing the costs and the uncertainties. Hence the focus on improving the quality and quantity of the fiber for pulping and decreasing the costs of pulping; a transgenic with such properties would require only APHIS oversight.

The industry appears to have a preference for a two-step regulatory system, in which a preliminary assessment by the regulatory authority would provide an initial determination of the nature of the transgenic plants' characteristics. Plants whose attributes were associated with environmental problems would then undergo through a more intensive and costly assessment and review, and other plants could be deregulated through a less rigorous system.

International Markets

Deregulation of a transgenic tree in the United States does not guarantee that it can be planted in other countries. As discussed above, many other countries have their own regulatory systems, including prohibitions on planting transgenics. Brazil's prohibition on transgenic crops was widely violated, and the Brazilian restrictions may be lifted for some transgenics, including trees. Chile also has a prohibition on the commercial use of transgenics, although it does allow regulated field-testing of some genetically modified plants.

Such a fragmentation of the worldwide market limits the potential for developers of transgenic trees. A study conducted in the past few years (Sedjo 1999) estimated that the potential market for an herbicide-resistant transgenic is large, but regulations abroad severely constrict the accessible market and thus the potential financial returns to the innovation. At the current time there appears to be relatively little research on applying the herbicide-resistant gene in trees, most of it at universities.

Given the problems in international markets for commercial transgenic seedlings, developers appear to be focusing on specific country markets. For example, much of the research by ArborGen focuses on loblolly pine, which is the dominant tree planted in the United States. Similarly, Cellfor, although not constrained by transgenic considerations, is focusing its cloning procedures on pine, an area that offers a large U.S. market as well as substantial foreign potential. New Zealand transgenic tree developers are focusing on the *radiata* pine, which is the dominant planted tree in that country. Additionally, there appears to be a substantial amount of research outside the United States on developing transgenic eucalyptus with enhanced fiber content; the intended markets are the large-scale eucalyptus plantations of Brazil and elsewhere.

13. Summary and Conclusions

As demonstrated in this report, transgenics have the potential to solve several problems in forestry. They may increase the productivity of industrial wood. Transgenics also have potential environmental benefits both by taking harvesting pressure off of old-growth and nature forests, which are desired for environmental values, as well as for assisting in the restoration of certain diseased species. As in agriculture, biotechnology and transgenics in forestry are controversial.

A regulatory system exists in the United States for assessing the safety and environmental impacts of transgenics, including trees. This system has a substantial history with crops, but a much shorter history with trees. Additionally, trees have some features that are different from most crops. A greater understanding of the operation of the regulatory system as applied to trees under PPA promises to increase social understanding of the system. The outputs of this research project should be useful to assist policymakers in assessing the adequacy of the current PPA and the regulatory processes that come out of the Act, as applied to transgenic trees. Additionally, this paper should provide insights as to the confidence and attitudes of various involved groups towards the regulatory system and the PPA as practiced.

Transgenics offer opportunities to increase productivity in forestry through innovations like those already developed for crops—herbicide and pest resistance—and through innovations involving trees form and fiber characteristics. Although the economics of tree improvement must account for long delays between innovation and the realization of financial benefits, genetic modification also promises the early capture of some benefits. Thus far, however, there have been no completed petitions for deregulation and, thus, the United States regulatory system has not yet been fully applied on a transgenic timber tree, although a precedent of sorts has been established with the orchard tree, the papaya.

Forestry will undoubtedly continue its transition from harvesting natural forests to tree cropping. As it does the potential of plant improvements to generate social and economic benefits increases. These improvements are being noted, not only in the United States, but also throughout the world. The United States is only one of several countries where forestry is important and where research is underway on transgenic timber trees.

Regardless of what form these benefits take, and indeed regardless of the behavior of the regulatory authorities in the United States, transgenics will undoubtedly have an important role in forestry somewhere in the world in the foreseeable future.

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Acronyms

APHIS	Animal and Plant Health Inspection Service
BT	*Bacillus thuringiensis*
EIS	environmental impact assessment
EPA	Environmental Protection Agency
EU	European Union
FDA	Food and Drug Administration
FIFRA	Federal Insecticide, Fungicide, and Rodenticide Act
GE	genetically engineered
GMO	genetically modified organism
NAS	National Academies of Science
NEPA	National Environmental Policy Act
PPA	Plant Protection Act
PRSV	papaya ring spot virus
TSCA	Toxic Substances Control Act
USDA	U.S. Department of Agriculture

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